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| 10/578,215 | 06/11/2007 | Andrew Scully | 28616-003 NATL | 7550 |
| 30623 7590 04/23/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C ONE FINANCIAL CENTER BOSTON, MA 02111 | | | | |
| EXAMINER | | | | |
| SMITH, PRESTON | | | | |
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| 1794 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,215

Applicant(s)

SCULLY ET AL.

Examiner

PRESTON SMITH

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 12/14/2007/07/26/2006
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation, "wherein the microbiological spore is partially germinated" however the claim does not specify when the germination occurs (ie before processing, during processing, or after). For purposes of compact prosecution, it has been considered that the germination to which applicant refers happens before processing.

Claim 15 provides for the use of an oxygen scavenger for inactivating a microbiological spore, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 18 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Michael J. Wilson, US-Patent 6,207,215 in view of Michael Laurence Rooney, US-Patent 6,601,732.

Regarding claims 14 and 18, Wilson teaches sterilizing and processing foods (particularly canned (column 3, line 55) or placed in pouches (column 7, line 32)) by treating the heated food at high pressures (*examiner notes applicant defines high pressures as 100-1000 MPa on page 1, line 7 of applicant's specification*) of 50,000-150,000 psi (or 344.7 MPa - 1034 MPa) after it has been packaged (column 3, lines 63-67). The sterilization process inactivates microbiological spores on food (column 3, line 24). The resulting sterilized food product would be the product of claims 14 and 18 (even though oxygen is not removed, the resulting product of Wilson would still be a sterile food product that meets the limitations of claims 14 and 18. Oxygen addition is only considered to maintain sterility).

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 9-13, 16-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Michael J. Wilson, US-Patent 6,207,215 in view of Michael Laurence Rooney, US-Patent 6,601,732.

Regarding claims 1-3, 5,10-13,16-17, Wilson teaches sterilizing and processing foods (particularly canned (column 3, line 55) or placed in pouches (column 7, line 32)) by treating the heated food at high pressures (*examiner notes applicant defines high pressures as 100-1000 MPa on page 1, line 7 of applicant's specification*) of 50,000-150,000 psi (or 344.7 MPa - 1034 MPa) after it has been packaged (column 3, lines 63-67). The sterilization process inactivates microbiological spores on food(column 3, line 24).

Wilson fails to teach removing oxygen from the environment of the food in the package.

Rooney teaches that it is well known in the art to use oxygen scavenger compositions (comprising a quinone such as benzoquinone) in food packaging to reduce oxygen content in the packaging (see Fig 1A-C, Fig 7, column 6, lines 65-67, column 7, line 30, column 10, line 47). It would have been obvious to one having ordinary skill in the art at the time of the invention to add an oxygen scavenger composition to the invention of Wilson (for example, coating the can or pouches (column 7, line 30 of Rooney) of the packaged food product of Wilson with the scavenger) since the oxygen scavenger composition would serve to reduce the oxygen content of the environment of the food and thus reduce the harmful effects oxygen has on food (column 1, lines 18-23 of Rooney) and allow for longer storage life of the food of Wilson.

Regarding claim 4, it would have thus been obvious to one having ordinary skill in the art to introduce the scavenger material (into the packaging of Wilson) to remove the oxygen in the atmosphere surrounding the food prior to the high pressure treatment process since introducing the scavenger material to remove the oxygen after high pressure treatment (of Wilson) wouldn't be efficient because this would require reopening the packaging after it has been sterilized with high pressure which would expose the food product to microbes and reduce the effectiveness of the sterilization process.

Regarding claim 9, the references do not explicitly state that the spores are partially germinated however germination has multiple stages ultimately resulting in the production of new cells. It is considered that since microbial growth (or reproduction) happens quite frequently and since microbes exists in amounts well in excess of 100,000 on the surface of food products, some of the microbial spores on the food would be in a stage of partial germination (in one of the multiple stages of germination) prior to the food being treated.

Claims 14 and 18 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Michael J. Wilson, US-Patent 6,207,215 in view of Michael Laurence Rooney, US-Patent 6,601,732.

Regarding claims 14 and 18, Wilson teaches sterilizing and processing foods (particularly canned (column 3, line 55) or placed in pouches (column 7, line 32)) by treating the heated food at high pressures (*examiner notes applicant defines high pressures as 100-1000 MPa on page 1, line 7 of applicant's specification*) of 50,000-150,000 psi (or 344.7 MPa - 1034 MPa) after it has been packaged (column 3, lines 63-67). The sterilization process inactivates microbiological spores on food(column 3, line 24) resulting in a sterilized packaged food product.

Wilson fails to teach removing oxygen from the environment of the food in the package.

Rooney teaches that it is well known in the art to use oxygen scavenger compositions (comprising a quinone such as benzoquinone) in food packaging to reduce oxygen content in the packaging (see Fig 1A-C, Fig 7, column 6, lines 65-67, column 7, line 30, column 10, line 47). It would have been obvious to one having ordinary skill in the art at the time of the invention to add an oxygen scavenger composition to the invention of Wilson (for example, coating the can or pouches (column 7, line 30 of Rooney) of the packaged food product of Wilson with the scavenger) since the oxygen scavenger composition would serve to reduce the oxygen content of the environment of the food and thus reduce the harmful effects oxygen has on food (column 1, lines 18-23 of Rooney) and allow for longer storage life of the food of Wilson.

Claims 6-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Michael J. Wilson, US-Patent 6,207,215 in view of Michael Laurence Rooney, US-Patent 6,601,732 and Edmund Y. Ting, US-Patent 5,316,745.

Regarding claims 6-8, the references teach the invention discussed previously and in particular, Wilson teaches pressure treating foods that have a pH of greater than 4.6 (column 4, line 40-41) such as main meals, sauces, soups, stews, etc. (column 4, lines 35-37).

The references fail to teach treating foods that have a pH of less than 4.6.

Ting teaches that it is well known in the art to pressure treat acidic foods such as peaches (known to have a pH from 3.7-4.2) with high pressures (120,000 psi or 827 MPa) in order to preserve them (column 1, lines 15-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to use foods with a pH of less than 4.6 such as pears with the composite invention of Wilson in view of Rooney since this would expand the variety of foods capable of use with the composite invention of Wilson in view of Rooney and thus make the invention of Wilson in view of Rooney more profitable.

[examiner notes that Wilson states that foods with a pH less than 4.6 are not prone to the growth of pathogens and thus implies that the pressure treatment process would not be necessary for foods with a pH of 4.6 or less since there would be no pathogen growth to inhibit. Ting however teaches that high pressure treatment such as the one taught by Wilson is favorable even for highly acidic foods (such as peaches) that naturally inhibit microbial growth (column 1, lines 20-23). Additionally, it is considered that adding the pressure treatment step even for the acidic foods would provide an added degree of certainty that any spores/microbes present on food are completely inhibited]

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRESTON SMITH whose telephone number is (571)270-7084. The examiner can normally be reached on Mon-Th 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Drew E Becker/
Primary Examiner, Art Unit 1794

prs